K090782

510(k) SUMMARY

APR 22 2009

Novel® ALIF Spinal Spacer System
510(k) SUMMARY
March 2009

Company: Alphatec Spine, Inc.
5818 El Camino Real
Carlsbad, CA 92008 USA
Direct: (760) 494-6771
Fax: (760) 431-0289

Contact Person: Mary Stanners, Regulatory Affairs Specialist II

Trade/Proprietary Name: Novel® ALIF Spinal Spacer System

Common Name: Intervertebral Body Fusion Device
Vertebral Body Replacement Device

Classification Name: Intervertebral Body Fusion Device
Spinal Intervertebral Body Fixation Orthosis

Classification Number(s)/Product Code(s): 21 CFR 888.3080 (MAX)
21 CFR 888.3060 (MQP)

Product Description:

The Novel® ALIF Spinal Spacer System is an implantable device manufactured from PEEK and titanium alloy that is available in a variety of different shapes and sizes to suit individual pathology and anatomical conditions of the patient.

Indications for Use:

When used as an Intervertebral Body Fusion device, the Novel ALIF Spinal Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The Novel ALIF Spinal Spacer System is to be used with a supplemental fixation system and autogenous bone graft.

When used as a Vertebral Body Replacement device, the Novel ALIF Spinal Spacer System is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e. fracture). The Novel ALIF Spinal Spacer System is intended for use with supplemental spinal fixation system and allogenous bone graft. Specifically the Novel ALIF Spinal Spacer System is to be used with Alphatec Zodiac Polyaxial Spinal Fixation System or the Alphatec Mirage Top Tightening Spinal System.

Substantial Equivalence:

Data was provided which demonstrated the Novel ALIF Spinal Spacer System to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in indications for use, design, material and function.

Performance Data:

The test results demonstrate that the mechanical performance of the Novel ALIF Spinal Spacer System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alphatec Spine, Inc
% Ms. Mary Stanners
Regulatory Affairs Specialist II
5818 EL Camino Road
Carlsbad, California 92008

APR 22 2009

Re: K090782
Trade/Device Name: Novel® ALIF Spinal Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX, MQP
Dated: March 20, 2009
Received: March 23, 2009

Dear Ms. Stanners:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K090782

Device Name: Novel® ALIF Spinal Spacer System

Indications for Use:

Intervertebral Body Fusion

When used as an Intervertebral Body Fusion device, the Novel ALIF Spinal Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The Novel ALIF Spinal Spacer System is to be used with a supplemental fixation system and autogenous bone graft.

Vertebral Body Replacement

When used as a Vertebral Body Replacement device, the Novel ALIF Spinal Spacer System is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e. fracture). The Novel ALIF Spinal Spacer System is intended for use with supplemental spinal fixation system and allogenous bone graft. Specifically-the Novel ALIF Spinal Spacer System is to be used with Alphatec Zodiac Polyaxial Spinal Fixation System or the Alphatec Mirage Top Tightening Spinal System.

Prescription Use ___X___ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K090782

PG. 1 OF 1